



NDA 17-911/S-066

Merck Research Laboratories  
Attention: Michelle W. Kloss, Ph.D.  
BLA-20  
West Point, PA 19486-0004

Dear Dr. Kloss:

Please refer to your supplemental new drug application dated August 21, 1998, received August 24, 1998 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clinoril (sulindac) Tablets.

We acknowledge receipt of your submissions dated October 28, 1998.

This "Changes Being Effected" supplemental new drug application provides for the addition of a Geriatrics Use subsection as a component of the PRECAUTIONS section to comply with the Geriatric Final Rule [201.57(f)(10)].

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 28, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Food and Drug Administration  
Rockville MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Chief Project Management Staff, at (301) 827-2125.

Sincerely,

*{See appended electronic signature page}*

Jonca Bull, M.D.  
Acting Director  
Division of Anti-Inflammatory, Analgesic and Ophthalmic  
Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

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/s/

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Jonca Bull  
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